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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,655	09/23/2003	Nyle S. Elliott	A-8601	9116
7590 04/23/2009 HOFFMAN, WASSON & GITLER, P.C. Suite 522 2361 Jefferson Davis Highway Arlington, VA 22202			EXAMINER MARCECICH, ADAM M	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 04/23/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/667,655

Applicant(s)

ELLIOTT, NYLE S.

Examiner

Adam Marcetich

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-12 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-12 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1, 2, 4, 6, 7 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravo; Biagio (US 5108430) in view of Millot P et al. (US 6171289).
 5. Regarding claims 1, 2, 4, 6, 7 and 21-24, Ravo discloses an alert device for detecting the presence of fecal matter comprising:

[1, 24] a pad having an aperture (col. 4, lines 1-12, Figs. 1, 2, support member 3 having cylindrical body portion 7 defining interior space);

[1, 24] an alarm attached to said pad (col. 5, lines 25-48, especially lines 25-29);

[1, 24] a first and second conductor extending from said aperture to said alarm (col. 5, lines 25-48, especially lines 33-40, electrical circuit, wires not shown; Examiner notes that an electrical circuit requires at least two conductors);

[1, 24] a plug (col. 4, lines 1-12, Figs. 1, 2, disc-shaped plug 5); and

[1, 24] said plug removably secured to said pad at said aperture (col. 4, lines 33-41);

[2] wherein said alarm emits an audible alarm (col. 5, lines 58-62);

[4] wherein said alarm emits a tactile alarm (col. 2, lines 62-64, col. 5, lines 25-48, signal transmitted to patient's skin);

[6] wherein said plug is secured in said aperture by mating threads (col. 4, lines 33-41, Figs. 1, 2, threaded portions 17 and 23);

[7] wherein said pad is a flexible, elastomeric material (cols. 4-5, lines 58-2, 7-13, reticulated polyurethane); and

[22] a plug having inner and outer surfaces (col. 4, lines 33-41, Fig. 2, inner surface as depicted below and threaded portion 17).

Ravo discloses the invention substantially as claimed, see above. However, Ravo lacks third and fourth conductors as claimed [claims 1 and 21-24].

Millot discloses a device for securing an ostomy bag about a stoma and emitting an alarm (col. 2, lines 3-18, col. 3, lines 19-22, Fig. 1, device 1), comprising a pad having an aperture (col. 3, lines 23-25 and Figs. 1 and 2, ostomy seal 5 having through passage 8).

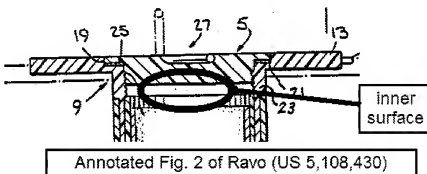
[21-24] Ravo and Millot detect different conditions and alert a user to the presence of fecal matter or moisture in an ostomy device. Ravo detects a distended colon (col. 5, lines 43-48), while Millot senses the moisture content of an ostomy seal (col. 3, lines 60-65). Both place electrical contacts exclusively within a pad member. That is, the conductors of Ravo and Millot do not extend to third and fourth conductors. Therefore, both lack third and fourth conductors on a plug as claimed [claims 1 and 21-24].

A rearrangement of conductors from a pad member to a plug is not sufficient to distinguish over prior art. One would be motivated to modify to conductors of Ravo and Millot to detect wetness or fecal matter in a desired location since the colon may not distend sufficiently to trigger the alarm of Ravo. That is, by extending third and electrical conductors within the plug of Ravo, wastes can be detected within a plug even when a colon does not distend enough to trigger an alarm.

Regarding a limitation of third and fourth conductors comprising a pair of spaced apart rings, Millot suggests that ring are a suitable shape for spacing conductors about an aperture (col. 3, lines 39-45, Fig. 2, electrodes 17, 18 on tracks 15 and 16 forming circle arc). The claimed "upwardly extending section" between upper and lower rings of claims 21 and 22, along with the "first section" of claim 23 are interpreted as auxiliary or supporting connections lacking criticality. For example, Ravo expedites disclosure by briefly referring to additional or supplementary or secondary conductors and does not depict them (col. 5, lines 33-40).

Additionally, a limitation of a plug having a lumen [claim 22] provides clearance for wastes to contact conductive surfaces. That is, a cylindrical depression or cavity ensures space for wastes to move through the cylinder and contact sensors before reaching the furthest distal edge.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to rearrange the conductors of Ravo and Millot in order to detect wastes that have contacted a plug and not sufficiently distended a colon. See MPEP 2144.04(VI)(C).



6. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Ravo; Biagio (US 5108430) in view of Millot P et al. (US 6171289), further in view of Johnson (US 5266928).

7. Regarding claims 3 and 5, Ravo in view of Millot discloses the invention as substantially claimed, see above. However, Ravo in view of Millot lacks a visible alarm or transmitted signal as claimed [claims 3 and 5]. Johnson discloses an alert device wherein the alarm emits a visible alarm or transmits a signal to a remote location

(column 8, lines 1-13). Johnson provides the advantage of providing multiple channels to alert a caregiver or user. For example, a user with either impaired vision or hearing may rely more heavily on either audio or visual clues. Transmitting to a remote location provides the advantage of allowing caregivers to leave the user's immediate area. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Ravo in view of Millot as discussed with the alarms as taught by Johnson in order to effectively alert a caregiver or user.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Ravo; Biagio (US 5108430) in view of Millot P et al. (US 6171289), further in view of Kim (US 5569216).

9. Regarding claim 8, Ravo in view of Millot discloses the invention as substantially claimed, see above. However, Ravo in view of Millot lacks an inflatable cuff as claimed [claim 8]. Kim discloses an inflatable cuff encircling a plug (column 2, lines 61-67 through column 3, lines 1-2 and Figs. 1-2, external balloon 100). Kim provides the advantage of preventing leakage of gases and liquids (column 1, lines 7-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Ravo in view of Millot as discussed with the inflatable cuff as taught by Kim in order to prevent leakage.

10. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Ravo; Biagio (US 5108430) in view of Millot P et al. (US 6171289), further in view of von Dyck (US 6350255).

11. Regarding claim 10, Ravo in view of Millot discloses the invention substantially as claimed, see above. However, Ravo in view of Millot lacks an absorbent sleeve as claimed [claim 10]. von Dyck discloses an absorbent sleeve disposed about a tube (column 13, lines 50-57 and Figs. 1-3, bolster 16 comprising foam surrounding catheter 14).

Von Dyck provides the advantage of absorbing any waste materials that may bypass sealing means of Ravo. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Ravo in view of Millot as discussed with the absorbent sleeve as taught by von Dyck in order to absorb any additional waste materials.

12. Regarding claim 11, Ravo in view of Millot discloses the invention substantially as claimed, see above. However, Ravo in view of Millot lacks a filter as claimed [claim 11]. Von Dyck discloses a plug including a filter (column 8, lines 38-49, especially lines 47-49, filter (not shown) within port 52 of catheter 14). von Dyck provides the advantage of filtering any flatus gases that are received within a chamber as during normal use. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Ravo in view of Millot as discussed with the filter as taught by von Dyck in order to filter flatus gases.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Ravo; Biagio (US 5108430) in view of Millot P et al. (US 6171289), further in view of McDonnell (US 4121589).

14. Regarding claim 12, Ravo in view of Millot discloses the invention as substantially claimed, see above. However, Ravo in view of Millot lacks an adhesive ring as claimed [claim 12]. McDonnell discloses an adhesive ring attached to one side a pad (column 3, lines 54-56 and Fig. 1, adhesive material 9). McDonnell provides the advantage of providing additional sealing force between a user and waste collection device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Ravo in view of Millot as discussed with the adhesive ring as taught by McDonnell in order to provide additional sealing force. In this modification, adhesive material 9 is placed about an outer flange 13 of Ravo.

Response to Amendment

15. Applicant has amended claims 1 and 24, filed 03 February 2009, to include the limitations of claims 9 and 21-24 which were previously objected to. Claim 24 has been amended to include the limitations of claim 9. Claim 9 has been canceled.

16. The following Office Action contains rejections to previously allowed and/or previously objected-to-as-allowable material as indicated in Office Action mailed 02 January 2009. Accordingly, the following action has been made Non-Final.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- | | |
|------------------------------|------------|
| ◆ Thompson; Ronald J. et al. | US 6021781 |
| ◆ Norris; Steven A. | US 4909263 |
| ◆ Kline; M. J. et al. | US 5264830 |

18. Examiner has applied new grounds of rejection to previously objected-to-as-allowable material. Therefore, this Office Action is Non-Final.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
21 April 2009